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			ART UNIT 1656	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/612,466

Applicant(s)

MADISON ET AL.

Examiner

Sheridan L. Swope

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-121 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-121 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Claims 1-121 are pending.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-38 and 119-121, drawn to a CVSP16 protease polypeptide, classified in class 435, subclass 226.
- II. Claims 39-56, drawn to a polynucleotide encoding a CVSP16 protease polypeptide, vector, host cell, and method of making the polypeptide, classified in class 536, subclass 23.2.
- III. Claims 57-64, drawn to an antibody to a CVSP16 protease polypeptide, classified in class 530, subclass 389.1.
- IV. Claims 65 and 118, drawn to a CVSP16 protease polypeptide linked to a targeting agent, classified in class 435, subclass 69.7.
- V. Claims 66-70, drawn to a composition comprising a modulator of a CVSP16 protease polypeptide, classified in class 435, subclass 226.
- VI. Claims 71-73, drawn to an array comprising a CVSP16 protease polypeptide, classified in class 436, subclass 86.
- VII. Claims 74 and 75, drawn to a method for identifying a modulator of a CVSP16 protease polypeptide, classified in class 435, subclass 23.
- VIII. Claims 76-79, drawn to a high-throughput method for identifying a modulators of CVSP16 protease polypeptides, classified in class 435, subclass 23.

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- IX. Claims 80-82, drawn to a method for identifying a binding partner of a CVSP16 protease polypeptide, classified in class 435, subclass 23.
- X. Claims 83 and 84, drawn to a high-throughput method for identifying binding partners of CVSP16 protease polypeptides, classified in class 435, subclass 23.
- XI. Claims 85-87, drawn to a method for identifying an activator of a zymogen form of a CVSP16 protease polypeptide, classified in class 435, subclass 23.
- XII. Claims 88-90, drawn to a method of treating a neoplastic disease using a modulator of a CVSP16 protease polypeptide, classified in class 514, subclass 1.
- XIII. Claims 91-95 and 108-111, drawn to a method of treating a tumor using a modulator of activation cleavage of a zymogen form of a CVSP16 protease polypeptide, classified in class 514, subclass 1.
- XIV. Claim 96, drawn to a method of determining whether a binding partner of a CVSP16 protease polypeptide affects the function thereof, classified in class 435, subclass 23.
- XV. Claims 97-107, drawn to a method of diagnosis by detecting a CVSP16 protease polypeptide, classified in class 435, subclass 7.1.
- XVI. Claims 112-114, drawn to a signal sequence peptide, classified in class 530, subclass 326.
- XVII. Claim 115, drawn to a computational method for identifying a binding partner of a CVSP16 protease polypeptide, classified in class D14, subclass 485.
- XVIII. Claims 116 and 117, drawn to a transgenic animal, classified in class 800, subclass 8.

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For each of Inventions I-VI above, restriction to one of the following is also required under 35 USC 121. Therefore, election is required of one of Inventions I-VI and one or more of Inventions (A)-(DDDDDDDD), as indicated.

If Invention I is elected, elect one of:

- (A.) One specific polypeptide comprising a protease domain of a serine protease 16 (CVSP16) or a functionally active portion thereof or a domain thereof, wherein if the polypeptide includes residues that correspond to Gln660 and Met661, it does not include at least 5 contiguous amino acids from SEQ ID No. 21 inserted between residues that correspond to Gln660 and M661 of SEQ ID No. 21
- (B.) One specific polypeptide comprising at least two protease domains of a serine protease 16 (CVSP16), wherein the polypeptide comprises at least 5 contiguous amino acids
- (C.) One specific polypeptide corresponding to residues 508-544 of SEQ ID No. 6
- (D.) One specific polypeptide comprising contiguous sequence Asn Asp Ser
- (E.) One specific polypeptide comprising Trp Asn Asp in the second protease domain
- (F.) One specific polypeptide comprising Ser Cys Trp Asn Asp Ser in the second protease domain
- (G.) One specific polypeptide comprising Cys Trp Asn Asp Ser in the second protease domain

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- (H.) One specific polypeptide comprising Gln Thr His in the second protease domain
- (I.) One specific polypeptide comprising Leu Gln Thr His in the second protease domain
- (J.) One specific polypeptide comprising residues 323-550 of SEQ ID NO: 6
- (K.) One specific polypeptide comprising residues 326-550 of SEQ ID NO: 6
- (L.) One specific polypeptide comprising residues 46-286 of SEQ ID NO: 6
- (M.) One specific polypeptide not comprising at least 5 contiguous residues of SEQ ID NO: 21
- (N.) One specific polypeptide comprising residues 658-663 of SEQ ID NO: 6
- (O.) One specific polypeptide comprising a protease domain of a CVSP16 or a specific active fragment thereof
- (P.) One specific polypeptide comprising residues 24-752 of SEQ ID NO: 6
- (Q.) Wherein the polypeptide is one chain
- (R.) Wherein the polypeptide is two chains
- (S.) Wherein the polypeptide is three chains
- (T.) Wherein the polypeptide is one chain
- (U.) The polypeptide of SEQ ID NO: 6/encoded by SEQ ID NO: 5
- (V.) One specific polypeptide wherein an unpaired cysteine residue is replaced

If (V) is elected, elect one of:

- a. Cys159
- b. Cys430

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- (W.) A polypeptide comprising residues 47-286 of SEQ ID NO: 6
- (X.) A polypeptide comprising residues 47-550 of SEQ ID NO: 6
- (Y.) One specific polypeptide that is specific combination of (A)-(X).

If Invention II is elected, elect one of:

- (Z.) One specific polypeptide comprising a protease domain of a serine protease 16 (CVSP16) or a functionally active portion thereof or a domain thereof, wherein if the polypeptide includes residues that correspond to Gln660 and Met661, it does not include at least 5 contiguous amino acids from SEQ ID No. 21 inserted between residues that correspond to Gln660 and M661 of SEQ ID No. 21
- (AA.) One specific polypeptide comprising at least two protease domains of a serine protease 16 (CVSP16), wherein the polypeptide comprises at least 5 contiguous amino acids
- (BB.) One specific polypeptide corresponding to residues 508-544 of SEQ ID No. 6
- (CC.) One specific polypeptide comprising contiguous sequence Asn Asp Ser
- (DD.) One specific polypeptide comprising Trp Asn Asp in the second protease domain
- (EE.) One specific polypeptide comprising Ser Cys Trp Asn Asp Ser in the second protease domain
- (FF.) One specific polypeptide comprising Cys Trp Asn Asp Ser in the second protease domain

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- (GG.) One specific polypeptide comprising Gln Thr His in the second protease domain
- (HH.) One specific polypeptide comprising Leu Gln Thr His in the second protease domain
- (II.) One specific polypeptide not comprising at least 5 contiguous residues of SEQ ID NO: 21
- (JJ.) Wherein the polypeptide is one chain
- (KK.) Wherein the polypeptide is two chains
- (LL.) Wherein the polypeptide is three chains
- (MM.) Wherein the polypeptide is one chain
- (NN.) One specific polypeptide that is a specific combination of (Z)-(MM)

If Invention III is elected, elect one of an antibody that binds to:

- (OO.) One specific polypeptide comprising a protease domain of a serine protease 16 (CVSP16) or a functionally active portion thereof or a domain thereof, wherein if the polypeptide includes residues that correspond to Gln660 and Met661, it does not include at least 5 contiguous amino acids from SEQ ID No. 21 inserted between residues that correspond to Gln660 and M661 of SEQ ID No. 21
- (PP.) One specific polypeptide comprising at least two protease domains of a serine protease 16 (CVSP16), wherein the polypeptide comprises at least 5 contiguous amino acids
- (QQ.) One specific polypeptide corresponding to residues 508-544 of SEQ ID No. 6

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- (RR.) One specific polypeptide comprising contiguous sequence Asn Asp Ser
- (SS.) One specific polypeptide comprising Trp Asn Asp in the second protease domain
- (TT.) One specific polypeptide comprising Ser Cys Trp Asn Asp Ser in the second protease domain
- (UU.) One specific polypeptide comprising Cys Trp Asn Asp Ser in the second protease domain
- (VV.) One specific polypeptide comprising Gln Thr His in the second protease domain
- (WW.) One specific polypeptide comprising Leu Gln Thr His in the second protease domain
- (XX.) One specific polypeptide not comprising at least 5 contiguous residues of SEQ ID NO: 21
- (YY.) One specific polypeptide that comprises a single-chain form of protease domain 1 of CVSP1 polypeptide
- (ZZ.) One specific polypeptide that comprises a single-chain form of protease domain 2 of CVSP1 polypeptide
- (AAA.) One specific polypeptide that is a specific combination of (OO)-(AAA)

If Invention V is elected, elect one of a composition comprising:

- (BBB.) A modulator of activity
- (CCC.) A modulator of substrate binding
- (DDD.) A modulator of ligand binding

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- (EEE.) An anti-tumor agent
- (FFF.) An anti-angiogenic agent
- (GGG.) A specific combination of (BBB)-(GGG)

If Invention VI is elected, elect one of an array comprising:

- (HHH.) One specific polypeptide comprising a protease domain of a serine protease 16 (CVSP16) or a functionally active portion thereof or a domain thereof, wherein if the polypeptide includes residues that correspond to Gln660 and Met661, it does not include at least 5 contiguous amino acids from SEQ ID No. 21 inserted between residues that correspond to Gln660 and M661 of SEQ ID No. 21
- (III.) One specific polypeptide comprising at least two protease domains of a serine protease 16 (CVSP16), wherein the polypeptide comprises at least 5 contiguous amino acids
- (JJJ.) One specific polypeptide corresponding to residues 508-544 of SEQ ID No. 6
- (KKK.) One specific polypeptide comprising contiguous sequence Asn Asp Ser
- (LLL.) One specific polypeptide comprising Trp Asn Asp in the second protease domain
- (MMM.) One specific polypeptide comprising Ser Cys Trp Asn Asp Ser in the second protease domain
- (NNN.) One specific polypeptide comprising Cys Trp Asn Asp Ser in the second protease domain

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- (OOO.) One specific polypeptide comprising Gln Thr His in the second protease domain
- (PPP.) One specific polypeptide comprising Leu Gln Thr His in the second protease domain
- (QQQ.) One specific polypeptide not comprising at least 5 contiguous residues of SEQ ID NO: 21
- (RRR.) One specific serine protease domain
- (SSS.) A specific combination of (HHH)-(SSS)

If Invention VII is elected, elect one of identifying a modulator of:

- (TTT.) One specific polypeptide comprising a protease domain of a serine protease 16 (CVSP16) or a functionally active portion thereof or a domain thereof, wherein if the polypeptide includes residues that correspond to Gln660 and Met661, it does not include at least 5 contiguous amino acids from SEQ ID No. 21 inserted between residues that correspond to Gln660 and M661 of SEQ ID No. 21
- (UUU.) One specific polypeptide comprising at least two protease domains of a serine protease 16 (CVSP16), wherein the polypeptide comprises at least 5 contiguous amino acids
- (VVV.) One specific polypeptide corresponding to residues 508-544 of SEQ ID No. 6
- (WWW.) One specific polypeptide comprising contiguous sequence Asn Asp Ser
- (XXX.) One specific polypeptide comprising Trp Asn Asp in the second protease domain

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- (YYY.) One specific polypeptide comprising Ser Cys Trp Asn Asp Ser in the second protease domain
- (ZZZ.) One specific polypeptide comprising Cys Trp Asn Asp Ser in the second protease domain
- (AAAA.) One specific polypeptide comprising Gln Thr His in the second protease domain
- (BBBB.) One specific polypeptide comprising Leu Gln Thr His in the second protease domain
- (CCCC.) One specific polypeptide not comprising at least 5 contiguous residues of SEQ ID NO: 21
- (DDDD.) One specific polypeptide that is a specific combination of (TTT)-(CCCC)

If Invention IX is elected, elect one of identifying a binding partner of:

- (EEEE.) One specific polypeptide comprising a protease domain of a serine protease 16 (CVSP16) or a functionally active portion thereof or a domain thereof, wherein if the polypeptide includes residues that correspond to Gln660 and Met661, it does not include at least 5 contiguous amino acids from SEQ ID No. 21 inserted between residues that correspond to Gln660 and M661 of SEQ ID No. 21
- (FFFF.) One specific polypeptide comprising at least two protease domains of a serine protease 16 (CVSP16), wherein the polypeptide comprises at least 5 contiguous amino acids
- (GGGG.) One specific polypeptide corresponding to residues 508-544 of SEQ ID No. 6

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- (HHHH.) One specific polypeptide comprising contiguous sequence Asn Asp Ser
- (IIII.) One specific polypeptide comprising Trp Asn Asp in the second protease domain
- (JJJJ.) One specific polypeptide comprising Ser Cys Trp Asn Asp Ser in the second protease domain
- (KKKK.) One specific polypeptide comprising Cys Trp Asn Asp Ser in the second protease domain
- (LLLL.) One specific polypeptide comprising Gln Thr His in the second protease domain
- (MMMM.) One specific polypeptide comprising Leu Gln Thr His in the second protease domain
- (NNNN.) One specific polypeptide not comprising at least 5 contiguous residues of SEQ ID NO: 21
- (OOOO.) One specific polypeptide that is a proteolytically active fragment of (BBBB)-(KKKK)
- (PPPP.) One specific polypeptide that is a substrate binding fragment of (BBBB)-(KKKK)
- (QQQQ.) One specific polypeptide that is a ligand binding fragment of (BBBB)-(KKKK)
- (RRRR.) One specific polypeptide that is a specific combination of (EEEE)-(RRRR)

If Invention X is elected, elect a high-throughput method comprising a specific combination of (EEEE)-(RRRR) above.

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If Invention XI is elected, elect a zymogen form of:

- (SSSS.) One specific polypeptide comprising a protease domain of a serine protease 16 (CVSP16) or a functionally active portion thereof or a domain thereof, wherein if the polypeptide includes residues that correspond to Gln660 and Met661, it does not include at least 5 contiguous amino acids from SEQ ID No. 21 inserted between residues that correspond to Gln660 and M661 of SEQ ID No. 21
- (TTTT.) One specific polypeptide comprising at least two protease domains of a serine protease 16 (CVSP16), wherein the polypeptide comprises at least 5 contiguous amino acids
- (UUUU.) One specific polypeptide corresponding to residues 508-544 of SEQ ID No. 6
- (VVVV.) One specific polypeptide comprising contiguous sequence Asn Asp Ser
- (WWWW.) One specific polypeptide comprising Trp Asn Asp in the second protease domain
- (XXXX.) One specific polypeptide comprising Ser Cys Trp Asn Asp Ser in the second protease domain
- (YYYY.) One specific polypeptide comprising Cys Trp Asn Asp Ser in the second protease domain
- (ZZZZ.) One specific polypeptide comprising Gln Thr His in the second protease domain
- (AAAAA.) One specific polypeptide comprising Leu Gln Thr His in the second protease domain

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(BBBBB.) One specific polypeptide not comprising at least 5 contiguous residues of SEQ

ID NO: 21

(CCCCC.) One specific polypeptide comprising a specific combination of (SSSS)-

(CCCCC).

If Invention XII or XIII is elected, elect one of treatment with a modulator of:

(DDDDD.) One specific polypeptide comprising a protease domain of a serine

protease 16 (CVSP16) or a functionally active portion thereof or a domain

thereof, wherein if the polypeptide includes residues that correspond to

Gln660 and Met661, it does not include at least 5 contiguous amino acids

from SEQ ID No. 21 inserted between residues that correspond to Gln660 and

M661 of SEQ ID No. 21

(EEEE.) One specific polypeptide comprising at least two protease domains of a serine

protease 16 (CVSP16), wherein the polypeptide comprises at least 5

contiguous amino acids

(FFFFF.) One specific polypeptide corresponding to residues 508-544 of SEQ ID No. 6

(GGGGG.) One specific polypeptide comprising contiguous sequence Asn Asp Ser

(HHHHH.) One specific polypeptide comprising Trp Asn Asp in the second protease

domain

(IIIII.) One specific polypeptide comprising Ser Cys Trp Asn Asp Ser in the second

protease domain

(JJJJJ.) One specific polypeptide comprising Cys Trp Asn Asp Ser in the second

protease domain

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(KKKKK.) One specific polypeptide comprising Gln Thr His in the second protease domain

(LLLLL.) One specific polypeptide comprising Leu Gln Thr His in the second protease domain

(MMMMM.) One specific polypeptide not comprising at least 5 contiguous residues of SEQ ID NO: 21

(NNNNN.) One specific polypeptide comprising a specific combination of (DDDDD)-(NNNNN).

If Invention XIII is elected, also elect treatment one of the following diseases:

(OOOOO.) Uterus

(PPPPP.) Breast

(QQQQQ.) Colon

(RRRRR.) Lung

(SSSSS.) Kidney

(TTTTT.) Rectum

(UUUUU.) Prostate

(VVVVV.) Cervix

(WWWWW.) Testes

(XXXXX.) Stomach

(YYYYY.) Esophagus

(ZZZZZ.) Ovary

(AAAAA.) Small intestine

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(BBBBBB.) Leukemia

(CCCCCC.) lymphoma

If Invention XIV is elected, elect one of a binding partner of:

(DDDDDD.) One specific polypeptide comprising a protease domain of a serine protease 16 (CVSP16) or a functionally active portion thereof or a domain thereof, wherein if the polypeptide includes residues that correspond to Gln660 and Met661, it does not include at least 5 contiguous amino acids from SEQ ID No. 21 inserted between residues that correspond to Gln660 and M661 of SEQ ID No. 21

(EEEEEE.) One specific polypeptide comprising at least two protease domains of a serine protease 16 (CVSP16), wherein the polypeptide comprises at least 5 contiguous amino acids

(FFFFFF.) One specific polypeptide corresponding to residues 508-544 of SEQ ID No. 6

(GGGGGG.) One specific polypeptide comprising contiguous sequence Asn Asp Ser

(HHHHHH.) One specific polypeptide comprising Trp Asn Asp in the second protease domain

(IIIIII.) One specific polypeptide comprising Ser Cys Trp Asn Asp Ser in the second protease domain

(JJJJJJ.) One specific polypeptide comprising Cys Trp Asn Asp Ser in the second protease domain

(KKKKKK.) One specific polypeptide comprising Gln Thr His in the second protease domain

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(LLLLLL.) One specific polypeptide comprising Leu Gln Thr His in the second protease domain

(MMMMMM.) One specific polypeptide not comprising at least 5 contiguous residues of SEQ ID NO: 21

(NNNNNN.) One specific polypeptide comprising a specific combination of (DDDDDD)-(NNNNNN).

If Invention XV is elected, elect one of diagnosis by detecting one of:

(OOOOOO.) One specific polypeptide comprising a protease domain of a serine protease 16 (CVSP16) or a functionally active portion thereof or a domain thereof, wherein if the polypeptide includes residues that correspond to Gln660 and Met661, it does not include at least 5 contiguous amino acids from SEQ ID No. 21 inserted between residues that correspond to Gln660 and M661 of SEQ ID No. 21

(PPPPPP.) One specific polypeptide comprising at least two protease domains of a serine protease 16 (CVSP16), wherein the polypeptide comprises at least 5 contiguous amino acids

(QQQQQQ.) One specific polypeptide corresponding to residues 508-544 of SEQ ID No. 6

(RRRRRR.) One specific polypeptide comprising contiguous sequence Asn Asp Ser

(SSSSSS.) One specific polypeptide comprising Trp Asn Asp in the second protease domain

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(TTTTTT.) One specific polypeptide comprising Ser Cys Trp Asn Asp Ser in the second protease domain

(UUUUUU.) One specific polypeptide comprising Cys Trp Asn Asp Ser in the second protease domain

(VVVVVV.) One specific polypeptide comprising Gln Thr His in the second protease domain

(WWWWWW.) One specific polypeptide comprising Leu Gln Thr His in the second protease domain

(XXXXXX.) One specific polypeptide not comprising at least 5 contiguous residues of SEQ ID NO: 21

(YYYYYY.) One specific polypeptide comprising the protease domain of (OOOOOO)-(YYYYYY)

(ZZZZZZ.) One specific polypeptide comprising a specific combination of (OOOOOO)-(ZZZZZZ).

If Invention XV is elected, also elect one of diagnosis by detecting one of:

(AAAAAAA.) Amount of the specific polypeptide

(BBBBBBB.) Form of the specific polypeptide

(CCCCCCC.) Activity of the specific polypeptide

If Invention XVII is elected, elect one of a computational method for identifying a binding partner of:

(DDDDDDD.) One specific polypeptide comprising a protease domain of a serine protease 16 (CVSP16) or a functionally active portion thereof or a domain

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thereof, wherein if the polypeptide includes residues that correspond to Gln660 and Met661, it does not include at least 5 contiguous amino acids from SEQ ID No. 21 inserted between residues that correspond to Gln660 and M661 of SEQ ID No. 21

(EEEEEEE.) One specific polypeptide comprising at least two protease domains of a serine protease 16 (CVSP16), wherein the polypeptide comprises at least 5 contiguous amino acids

(FFFFFFF.) One specific polypeptide corresponding to residues 508-544 of SEQ ID No. 6

(GGGGGGG.) One specific polypeptide comprising contiguous sequence Asn Asp Ser

(HHHHHHH.) One specific polypeptide comprising Trp Asn Asp in the second protease domain

(IIIIIII.) One specific polypeptide comprising Ser Cys Trp Asn Asp Ser in the second protease domain

(JJJJJJJ.) One specific polypeptide comprising Cys Trp Asn Asp Ser in the second protease domain

(KKKKKKK.) One specific polypeptide comprising Gln Thr His in the second protease domain

(LLLLLLL.) One specific polypeptide comprising Leu Gln Thr His in the second protease domain

(MMMMMMM.) A specific polypeptide of (DDDDDDD)-(LLLLLLL) that contains one chain

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(NNNNNNN.) A specific polypeptide of (DDDDDDDD)-(LLLLLLL) that contains two chains

(OOOOOOO.) A specific polypeptide of (DDDDDDDD)-(LLLLLLL) that contains three chains

(PPPPPPP.) A specific polypeptide of (DDDDDDDD)-(LLLLLLL) that contains one protease domain

(QQQQQQQ.) A specific polypeptide comprising a specific combination of (DDDDDDDD)-(LLLLLLL).

If Invention XVIII is elected, elect one of a transgenic animal with inactivation of:

(RRRRRRR.) One specific polypeptide comprising a protease domain of a serine protease 16 (CVSP16) or a functionally active portion thereof or a domain thereof, wherein if the polypeptide includes residues that correspond to Gln660 and Met661, it does not include at least 5 contiguous amino acids from SEQ ID No. 21 inserted between residues that correspond to Gln660 and M661 of SEQ ID No. 21

(SSSSSSS.) One specific polypeptide comprising at least two protease domains of a serine protease 16 (CVSP16), wherein the polypeptide comprises at least 5 contiguous amino acids

(TTTTTTT.) One specific polypeptide corresponding to residues 508-544 of SEQ ID No. 6

(UUUUUUU.) One specific polypeptide comprising contiguous sequence Asn Asp Ser

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(VVVVVVV.) One specific polypeptide comprising Trp Asn Asp in the second protease domain

(WWWWWWW.) One specific polypeptide comprising Ser Cys Trp Asn Asp Ser in the second protease domain

(XXXXXXXX.) One specific polypeptide comprising Cys Trp Asn Asp Ser in the second protease domain

(YYYYYYY.) One specific polypeptide comprising Gln Thr His in the second protease domain

(ZZZZZZZ.) One specific polypeptide comprising Leu Gln Thr His in the second protease domain

(AAAAAAAA.) A specific polypeptide comprising a specific combination of (RRRRRRR)-(ZZZZZZZ)

(BBBBBBB.) A specific polypeptide of (RRRRRRR)-(ZZZZZZZ) that contains one chain

(CCCCCCC.) A specific polypeptide of (RRRRRRR)-(ZZZZZZZ) that contains two chains

(DDDDDDD.) A specific polypeptide of (RRRRRRR)-(ZZZZZZZ) that contains three chains.

Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Also, product and process inventions are distinct if any of the following can be shown: (1) that the process as claimed can be used to make another and

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materially different product, (2) that the product claimed can be used in a materially different process of using that product, or (3) that the product claimed can be made by another and materially different process (MPEP § 806.05(h)). These inventions are different or distinct for the following reasons.

The polynucleotide of Invention II is related to the polypeptide of Invention I by virtue of encoding the same. The DNA molecule has utility for the recombinant production of the polypeptide in host cells. Although the DNA molecule and polypeptide are related, since the DNA encodes the specifically claimed polypeptide, they are distinct inventions because they are physically and functionally distinct chemical entities, and the polypeptide product can be made by another and materially different process, such as by synthetic peptide synthesis or purification from the natural source. Further, the DNA may be used for processes other than the production of the polypeptide, such as in a nucleic acid hybridization assay.

The protein of Invention I is related to the antibody of Invention III by virtue of being the cognate antigen necessary for the production of antibodies. Although the protein and antibody are related, due to the necessary steric complementarity of the two, they are distinct inventions because they are physically and functionally distinct chemical entities and because the protein can be used in another and materially different process from the use for production of the antibody, such as in a pharmaceutical composition in its own right.

In addition to the distinction between the products of Invention I-III, as described above, Inventions I-VI, XVI and XVIII are distinct because the products of Inventions I-VI, XVI and XVIII are physically and functionally distinct chemical entities.

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Inventions VII-XV and XVII are independent because the methods of Inventions VII-XV and XVII comprise different steps, utilize different products and/or produce different results.

The methods of Invention VII-XV and XVII are distinct from the products of Inventions I-VI, XVI and XVIII because said method are not the only methods of making and/or using said products.

A search for more than one of Inventions I-XVIII would be a burden on the Office for the following reasons.

Because the products of Inventions I-VI, XVI and XVIII are structurally and/or functionally distinct entities, a search for one said invention would not encompass a search for any other invention and searching all of Inventions I-VI, XVI and XVIII, or a subset thereof would be a burden on the Office.

Because the methods of Inventions VII-XV and XVII comprise different steps, utilize different products, and/or produce different results, a search for one said invention would not encompass a search for any other invention and searching all of Inventions VII-XV and XVII, or a subset thereof would be a burden on the Office.

A search for the products of Inventions I-VI, XVI and XVIII would not encompass a search for the methods of Inventions VII-XV and XVII, or vice versa, because said methods are not the only methods of making and/or using said products. Thus, a search of any of Inventions I-VI, XVI and XVIII with any of Inventions VII-XV and XVII would be a burden on the Office.

These inventions are distinct for the reasons given above and have acquired a separate status in the art due to their recognized divergent subject matter, as shown by their different

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classification. Furthermore, as explained above, searching more than one invention would be a burden on the Office. Therefore, restriction for examination purposes, as indicated, is proper.

Restriction between product and process claims has been required. Where Applicant elects claims directed to a product, and the product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the Official Gazette notice dated March 26, 1996 (1184 O.G. 86; see also M.P.E.P. 821.04, *In re* Ochiai, and *In re* Brouwer). Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right, if the amendment is presented prior to final rejection or allowance, whichever is earlier. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. To be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan L. Swope whose telephone number is 571-272-0943. The examiner can normally be reached on M-F; 9:30-7 EST.


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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published application may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on the access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sheridan Lee Swope, Ph.D.

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SHERIDAN SWOPE, Ph.D.
PATENT EXAMINER